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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,294	12/05/2001	Jon A. Wolff	MIRUS.003.06.1	8816
25032	7590	04/26/2005		EXAMINER
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			DAVIS, BRIAN J	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/005,294	WOLFF ET AL.
Examiner	Art Unit	
Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/11/05 (RCE).
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 7 and 8 is/are allowed.
- 6) Claim(s) 6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |



DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/05 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by DE 1963399 A (CAPLUS abstract), of record. The reference teaches applicant's compound: RN=32797-22-1. Applicant's arguments accompanying the RCE have been carefully considered, but are not persuasive. The outstanding rejection is reproduced below and expanded to address these new arguments.

As was stated previously, during patent examination the pending claims must be given their broadest reasonable interpretation consistent with the specification. *In re Hyatt*, 211 F. 3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). To wit: applicant defines orthogonal protecting groups as "... a protective group that can be selectively

removed in the presence of other protective groups..." (page 22 line 30). Furthermore, applicant defines a protective group as "...a chemical group that is temporarily bound to functionalities within a multifunctional compound that allows selective reactions to take place at other sites..." (page 22 line 36).

The cited prior art, using the instant variable labels, has R= -C(O)(CH₂)₁₆Me and R'= -SO₃⁻. These groups are encompassed by applicant's definitions and may be considered as orthogonal protecting groups: They are different chemical moieties temporarily bound to a functionality (protective aspect; all chemical bonds can be thought of as temporary) and since they differ in structure and thus in properties, would be expected to behave differently under different reactions conditions (orthogonal aspect).

Applicant points out in the RCE that "protecting groups and orthogonal protecting groups are widely utilized and readily recognized tools in organic synthesis as evidenced by the texts: *Protecting Groups*, by Philip J. Kocienski; *Protecting Groups in Organic Synthesis*, by Theodora W. Greene and Peter G. M. Wuts; and *Organic Synthesis, The Science Behind the Art* (Chapter 2), by W. A. Smit et al." Applicant further notes that the second reference listed above provides in Chapter 7 a list of protecting groups for amines - which does not include -SO₃⁻ or a -C(O)(CH₂)₁₆Me as a protecting group. And the examiner is in perfect agreement with applicant with regard to these observations. However, the examiner is not in agreement that the above observations obviate the outstanding rejection.

Firstly, the term “protecting group” is a *concept* – as applicant implies in the argument outlined above, and indeed explicitly labels as such towards the end of the same paragraph: “...the *concept* [emphasis added] of protecting groups.” And this is exactly the examiner’s point, and the core of the rejection: the term “protecting group” is merely a concept. That is, the term describes a function, or a set of required properties or characteristics, of a substituent rather than being an explicit definition of the substituent itself. And this is also precisely why applicant will find no exhaustive list of permissible protecting groups for amines in the references cited above – or indeed, in any reference anywhere, ever. For one, the chemical arts are not static and a list of protecting groups compiled, for instance, 50 years ago will not match a list produced 50 years hence. And two, as argued above, the term “protecting group” is merely a concept, and as such may be defined without recourse to lists.

With specific regard to the instant groups in question ($-\text{SO}_3^-$ and $-\text{C}(\text{O})(\text{CH}_2)_{16}\text{Me}$), as previously stated, neither group appears in Chapter 7 of *Protecting Groups in Organic Synthesis*. However, the examiner points out that $-\text{C}(\text{O})(\text{CH}_2)_{16}\text{Me}$ is an example of an amide ($-\text{NC}(\text{O})\text{R}$); an old and well-known class of amine-protecting groups. The chemical arts contain innumerable examples of various amides as amine-protecting groups and the examiner will not further belabor this trivial point at this stage of the prosecution.

More interestingly, with regard to $-\text{SO}_3^-$, this group is also not listed in the table. But, this is irrelevant. The term “protecting group” is not defined or limited by the Chapter 7 table, or any table. It is limited just exactly as applicant says in the

specification it is limited: "...a protective group that can be selectively removed in the presence of other protective groups..." (page 22 line 30) where a protective group is defined as "...a chemical group that is temporarily bound to functionalities within a multifunctional compound that allows selective reactions to take place at other sites..." (page 22 line 36).

The group SO_3^- falls within that definition.

The rejection is maintained.

102 Rejections Withdrawn

The rejection of claim 8 under 35 USC 102(b), outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment transforms the claim to a related process claim. The rejection is untenable.

103 Rejections Withdrawn

The rejection of claim 8 under 35 USC 103(a), outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment transforms the claim to a related process claim. The rejection is untenable.

Allowable Subject Matter

Claims 7 and 8 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
April 20, 2005